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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,581	11/24/2003	Dan T. Simionescu	CXU-378	5668
22827	7590	08/01/2005		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/722,581	SIMIONESCU ET AL.
	Examiner	Art Unit
	Paul B. Prebilic	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 January 2005.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) 16-33 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12, 14 and 15 is/are rejected.

7) Claim(s) 13 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date various.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a bioprosthesis, classified in class 623, subclass 2.14.
- II. Claims 16-27, drawn to a process of making a bioprosthesis, classified in class 600, subclass 36.
- III. Claims 28-33, drawn to a process of using a bioprosthetic heart valve, classified in class 623, subclass 2.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I or III) and II are related as process of making and product made or used. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product made or used could be made by a materially different process such as a tubular piece of tissue could be provided instead of a sheet.

Inventions I and III are related as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed could be used in a materially different method such as one where a damaged valve is not removed or used in a different location in the body such as in a vein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Christina Mangelsen on July 21, 2005 a provisional election was made **without** traverse to prosecute the invention of Group I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 31, and 33-39 of copending Application No. 10/722,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are substantially identical except that the fixing agent of tannic acid is not taught by the present claims. However, the specific agent of tannic acid is considered *prima facie* obvious over the generic fixing agent of the present claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang (US 2003/0078659). Yang anticipates the claim language where the support material

as claimed is one of the layers of the multilayered device of Yang, or alternatively, the support material as claimed is the folded edge of Yang; see paragraphs [0025] and [0033] to [0035].

With regard to claims 1 and 2, the Examiner asserts that porcine vena cava tissue as disclosed by Yang inherently has greater than 30% by weight elastin content due to its elastic nature. And due to its similarity to the claimed material, it reasonably appears to have the claimed weight percent of elastin.

With regard to claims 3 and 4, since the stiffness and elasticity is not compared to any known value, it is considered inherently met by any material with some elasticity and stiffness. Furthermore, the Examiner asserts that the anisotropic property is inherent to the tissue because this limitation only requires that there be some non-uniformity in any characteristic. Since all materials have at least some slight non-uniformities, the claim language is considered inherently fully met.

Claims 1, 2, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregory (US 5,990,379). Gregory anticipates the claim language where the material produced by Gregory is an artificial tissue or modified natural tissue and it inherently contains close to 100% elastin since all other materials have been removed; see the abstract and column 4, line 15 to column 5, line 18.

With regard to claim 8, the stent of Gregory is considered to be a suture ring to the extent that this language can be given patentable weight because the stent can be used to attach sutures to the elastin tissue.

Claims 1-4, 8-11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen-Thien-Nhon (US 6,001,126). Nguyen-Thien-Nhon anticipates the claim language where the support material as claimed is the fabric (28) of Nguyen-Thien-Nhon and the elastin content is asserted to be inherently present in the tissues disclosed by Nguyen-Thien-Nhon; see the figures, the abstract, column 4, line 17 to column 5, line 33 and column 6, lines 7-52.

With regard to claim 8, the fabric (28) is considered to be a suture ring as claimed.

Claims 1-3, 7-11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grassi (US 4,655,773). Grassi anticipates the claim language where the pericardial tissue thereof is asserted to have at least 10% by weight elastin therein and the support structure as claimed is the stent; see the abstract, the figures, and columns 1 and 2 thereof.

#### ***Allowable Subject Matter***

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending

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claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738